

# TRANSMITTAL FORM

Application Number: 10/518,599  
 Filing Date: December 17, 2004  
 First Named Inventor: Joseph M. Penninger  
 Art Unit: 1651  
 Examiner Name: Unknown

Total Number of Pages in this Submission : \_\_\_\_\_

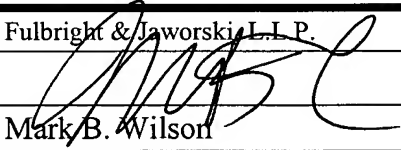
Attorney Docket Number: SONN:064US

## ENCLOSURES (check all that apply)

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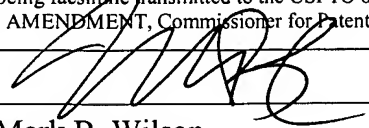
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Firm Name	Fulbright & Jaworski L.L.P.	Customer Number	32425
Signature			
Printed Name	Mark B. Wilson	Reg. No.	37,259
Date	August 9, 2005		

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Typed or Printed Name	Mark B. Wilson	Date	August 9, 2005



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Joseph M. Penninger *et al.*

Serial No.: 10/518,599

Filed: 12/17/04

For: ACE2 ACTIVATION FOR TREATMENT  
OF HEART, LUNG AND KIDNEY  
DISEASE AND HYPERTENSION

Group Art Unit: 1651

Examiner: UNKNOWN

Atty. Dkt. No.: SONN:064US

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Mark B. Wilson

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**MS AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner. Copies of cited U.S. patents, U. S. patent application publications and co-pending U.S. patent applications have not been enclosed subject to the waiver regarding the requirement



under 37 C.F.R. §1.98(a)(2)(i) stated in the Official Gazette Notice dated August 5, 2003 regarding patent applications filed on or after June 30, 2003.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Supplemental Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the filing of this Supplemental Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/SONN:064US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,

Mark B. Wilson  
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Attorney for Applicants

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Atty. Docket No.  
SONN:064USSerial No.  
10/518,599

List of Patents and Publications for Applicant's

Applicant  
Joseph M. Penninger et al.

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:  
December 17, 2004Group:  
1651U.S. Patent Documents  
*See Page 1*Foreign Patent Documents  
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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	4,708,871	11/24/87	Geysen, <i>et al.</i>	424	186.1	11/08/84
	A2	5,399,346	03/21/95	Anderson <i>et al.</i>	424	93.21	03/30/94
	A3	5,436,146	07/25/95	Shenk, <i>et al.</i>	435	457	01/21/93
	A4	5,529,774	06/25/96	Barba <i>et al.</i>	424	93.21	08/13/91
	A5	5,547,932	08/20/96	Curiel <i>et al.</i>	435	456	09/23/92
	A6	5,645,829	07/08/97	Shockley <i>et al.</i>	424	93.21	06/18/93
	A7	5,656,465	08/12/97	Panicali <i>et al.</i>	435	456	05/04/94
	A8	5,670,488	09/23/97	Gregory, <i>et al.</i>	514	44	10/13/93
	A9	5,672,344	09/30/97	Kelley, <i>et al.</i>	424	93.2	02/10/94
	A10	5,736,337	04/07/98	Avruch, <i>et al.</i>	435	7.1	06/10/94
	A11	5,741,486	04/21/98	Pathak <i>et al.</i>	424	93.21	06/06/95
	A12	5,767,075	06/16/98	Avruch <i>et al.</i>	514	12	06/02/95
	A13	5,792,851	08/11/98	Schuster, <i>et al.</i>	536	23.5	09/03/96
	A14	5,851,788	12/22/98	Fukuda, <i>et al.</i>	435	29	01/31/97
	A15	6,071,890	06/06/00	Scheule <i>et al.</i>	514	44	10/19/95
	A16	6,174,871	1/16/01	Hammond <i>et al.</i>	514	44	08/10/98
	A17	6,194,556	02/27/01	Acton <i>et al.</i>	536	23.2	12/11/97
	A18	6,224,584	5/1/01	Mach, <i>et al.</i>	604	508	05/04/99
	A19	6,306,830	10/23/01	Hammond <i>et al.</i>	514	44	01/16/98
	A20	6,322,536	11/27/01	Rosengart <i>et al.</i>	604	164.01	09/10/99
	A21	6,632,830	10/14/03	Acton, <i>et al.</i>	514	365	04/28/00

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List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Joseph M. Penninger et al.	
		Filing Date: December 17, 2004	Group: 1651
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**Foreign Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B2	WO 01/29040	4/24/01	WIPO			

**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

Exam. Init.	Ref. Des.	Citation
	C5	Altschul et al., "Basic local alignment search tool," <i>J. Mol. Biol.</i> , 215:403-410,1990.
	C6	Altschul et al., "Gapped blast and psi-blast: a new generation of protein database search programs," <i>Nucleic Acids Research</i> , 25:3389-3402,1997.
	C7	Andreoli et al., <i>Essentials of Medicine</i> , W.B. Saunders Company, 3:40-243,1993.
	C8	Carretero, et al., "Essential hypertension," <i>Circulation</i> , 101:329-335,2000.
	C9	Christian et al., "Simplified methods for construction, assessment and rapid screening of peptide libraries in bacteriophage," <i>J. Mol. Biol.</i> , 227:711-718.
	C10	Corvol et al., "Peptidyl-dipeptidase a/angiotensin i-converting enzyme," <i>Handbook of Proteolytic Enzyme 2<sup>nd</sup> Edn</i> , Elsevier Ltd., 82:332-346.
	C11	Corvol et al., "Peptidyl-dipeptidase a/angiotensin i-converting enzyme," <i>Clan MA-M2</i> , 359:1066-1076.
	C12	Cwirla et al., "Peptides on phage: a vast library of peptides for identifying ligands," <i>Biochemistry</i> , 87:6378-6382.
	C13	Donoghue et al., "A novel angiotensin-converting enzyme-related carboxypeptidase (ace2) converts angiotensin to angiotensin 1-9," <i>Circ. Res.</i> , 87:1-9,2000.
	C14	Elkind et al., "Stroke risk factors and stroke prevention," <i>Seminars in Neurology</i> , 18:429-439,1998.
	C15	Enseleit et al., "Vascular protective effects of angiotensin converting enzyme inhibitors and their relation to clinical events," <i>Journal of Cardiovascular Pharmacology</i> , 37:S21-S30,2001.
	C16	Esther et al., "Mice lacking angiotensin-converting enzyme have low blood pressure, renal pathology, and reduced mal fertility," <i>Laboratory Investigation</i> , 74:953-965,1996.
	C17	Figlin et al., "Technology evaluation: interleukin-2 gene therapy for the treatment of renal cell carcinoma," <i>Molecular Therapeutics</i> , 1:271-278.

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List of Patents and Publications for Applicant's

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## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

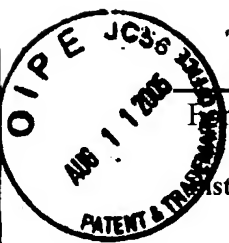
Exam. Init.	Ref. Des.	Citation
	C18	Franz <i>et al.</i> , "Analysis of tissue-specific gene delivery by recombinant adenoviruses containing cardiac-specific promoters," <i>Cardiovascular Research</i> , 35:560-566,1997.
	C19	Garg, <i>et al.</i> , "Overview of randomized trials of angiotensin-converting enzyme inhibitors on morality and morbidity in patients with heart failure," <i>Jama</i> , 273:1450-1456,1995.
	C20	Giordano <i>et al.</i> , "A cardiac myocyte vascular endothelial growth factor paracrine pathway is required to maintain cardiac function," <i>PNAS</i> , 98:5780-5785,2001.
	C21	Gish <i>et al.</i> , "identification of protein coding regions by database similarity search," <i>Nature Genetics</i> , 3:266-272,1993.
	C22	Herold <i>et al.</i> , "Herpes simplex virus as a model vector system for gene therapy in renal disease," <i>Kidney International</i> , 61:S3-S8,2002.
	C23	Heusch, "Hibernation Myocardium," <i>Physiological Reviews</i> , 78:1055-1085,1998.
	C24	Hilbert <i>et al.</i> , "Chromosomal mapping of two genetic loci associated with blood-pressure regulation in hereditary hypertensive rats," <i>Nature</i> , 353:521-528,1991.
	C25	Hollenberg, N.K. <i>et al.</i> , "Angiotensin converting enzyme inhibitor and the kidney," <i>Cardiology</i> , 3:S19-S29,1988.
	C26	Jacob, Howard, "Physiological Genetics," <i>Clinical and Experimental Pharmacology and Physiology and Physiology</i> , 26:530-535,1999.
	C27	Keitzmann <i>et al.</i> , "Induction of the plasminogen activator inhibitor-1 gene expression by mild hypoxia via a hypoxia response element binding the hypoxia-inducible factor-1 in rat hepatocytes," <i>Blood</i> , 94:4177-4185,1999.
	C28	Kloner <i>et al.</i> , "Medical and cellular implication of stunning, hibernation, and preconditioning," <i>Circulation</i> , 97:1848-1867,1998.
	C29	Klötting <i>et al.</i> , "Metabolic features of newly established congenic diabetes-prone bb.shr rat strains," <i>Life Science</i> , 62:973-979,1998.
	C30	Kong <i>et al.</i> , "Opgl is a key regulator of osteoclastogenesis, lymphocyte development and lymph-node organogenesis," <i>Nature</i> , 397:315-323,1999.
	C31	Krege <i>et al.</i> , "Male-female differences in fertility and blood pressure in ace-deficient mice," <i>Nature</i> , 375:146-148,1995.

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See Page 1Other Art  
See Page 1

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C32	Langer <i>et al.</i> , "Adeno-associated virus gene transferred into renal cells: potential for in vivo gene delivery," <i>Exp. Nephrol.</i> , 6:189-194,1998.
	C33	Lien <i>et al.</i> , "Gene therapy for renal disease," <i>Kidney International</i> , 52:S85-S88,1997.
	C34	Madden <i>et al.</i> , "Application of network blast server," <i>Methods in Enzymology</i> , 266:131-141,1996.
	C35	Murphy <i>et al.</i> , "Transgenic mouse model of stunned myocardium," <i>Science</i> , 287:488-490,2000.
	C36	Ohno <i>et al.</i> , "Cell-specific targeting of sindbis virus vectors displaying igg-binding domains of protein a," <i>Nature Biotechnology</i> , 15:763-767,1997.
	C37	Phillips <i>et al.</i> , "Vigilant vector: heart-specific promoter in an adeno-associated virus vector for cardioprotection," <i>Hypertension</i> , 39:651-655,2002.
	C38	Rapp, John P., "Genetic Analysis of Inherited Hypertension in the rat," <i>Physiological Reviews</i> , 80:135-172, 2000.
	C39	<i>Remington: The Science and Practice of Pharmacy</i> , Lippincott Williams and Wilkins, 14:186-200, Unknown Year.
	C40	Risch <i>et al.</i> , "No excess of homozygosity at loci used for dna fingerprinting," <i>Science</i> , 249:1416-1420,1990.
	C41	Rothmann <i>et al.</i> , "Heart muscle-specific gene expression using replication defective recombinant adenovirus," <i>Gene Therapy</i> , 3:919-926,1996.
	C42	Scott-Taylor <i>et al.</i> , "Adenovirus facilitated infection of human cells with ecotropic retrovirus," <i>Gene Therapy</i> , 5:621-629,1998.
	C43	Skeggs <i>et al.</i> , "The biochemistry of the renin-angiotensin system," <i>Adv Exp Med Biol.</i> 130:1-27,1980.
	C44	Sowter <i>et al.</i> , "Hif-1-dependent regulation of hypoxic induction of the cell death factors bnip3 and nix in human tumors," <i>Cancer Research</i> , 61:6669-6673,2001.
	C45	Stoll <i>et al.</i> , "A genomic-systems biology map for cardiovascular function," <i>Science</i> , 294:1723-1726,2001.
	C46	Tanimoto <i>et al.</i> , "Angiotensinogen-deficient mice with hypotension," <i>The Journal of Biological Chemistry</i> , 269:31334-31337,1994.

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Exam. Init.	Ref. Des.	Citation
	C47	Taylor <i>et al.</i> , "The acer gene of drosophila codes for an angiotensin-converting enzyme homologue," <i>Gene</i> , 181:191-197,1996.
	C48	Tipnis <i>et al.</i> , "A human homolog of angiotensin-converting enzyme," <i>The Journal of Biological Chemistry</i> , 275:33238-33243,2000.
	C49	Varda-Bloom <i>et al.</i> , "Tissue-specific gene therapy directed to tumor angiogenesis," <i>Gene Therapy</i> , 8:819-827,2001.
	C50	Vickers <i>et al.</i> , "Hydrolysis of biological peptides by human angiotensin-converting enzyme-related carboxypeptidase," <i>The Journal of Biological Chemistry</i> , 277:14838-14843,2002.
	C51	Weiss <i>et al.</i> , "Angiotensin II and atherosclerosis," <i>Am. J. Hum. Genet.</i> , 87:52C-32C, 2001.
	C52	Wickengarden <i>et al.</i> , "Targeted expression of a dominant-negative $k_v 4.2$ $k^+$ channel subunit in the mouse heart" <i>Circulation Research</i> , 85:1067-1076,1999.
	C53	Wuyts <i>et al.</i> , "Angiotensin i-converting enzyme insertion/deletion polymorphism: clinical implications," <i>Acta Clinica Belgica</i> , 52-6:338-349,1997.
	C54	Wyngaarden <i>et al.</i> , <i>Cecil Textbook of Medicine</i> , W.B. Saunders Company, 2:1272-1281,1992.
	C55	Yagil <i>et al.</i> , "Role of chromosome x in the sabra rat model of salt-sensitive hypertension," <i>Hypertension</i> , 33:261-265,1999.
	C56	Yangil <i>et al.</i> , "Development, genotype and phenotype of a new colony of that sabra hypertension prone (sbh/y) and resistant (sbn/y) rat model of salt sensitivity and resistance," <i>Journal of Hypertension</i> , 14:1175-1182, 1996.
	C57	Yusuf <i>et al.</i> , "Global burden of cardiovascular disease," <i>Circulation</i> , 104:2746-2753,2001
	C58	Zhang <i>et al.</i> , "Powerblast: a new network blast application for interactive or automated sequence analysis and annotation," <i>Genome Research</i> , 7:649-656,1997.
	C59	Zvaritch <i>et al.</i> , "The transgenic expression of highly inhibitory monomeric forms of phospholamban in mouse heart impairs cardiac contractility," <i>The Journal of Biological Chemistry</i> , 275:1485-14991,2000.

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